K102412

510(k) Summary

JUN 23 2011

Submitter/Applicant Name:	EyeQuick, LLC
Address:	1400 Common Drive El Paso, TX 79936 Phone number: (915) 490-1766 Fax number: (915) 975-8262 Contact: Marc Ellman, M.D.
Date prepared:	June 14, 2011
Trade name:	EyeQuick Digital Ophthalmoscope Camera
Classification name:	Ophthalmic Camera, AC-Powered 21 CFR Part 886.1120 Class II

Substantial equivalence claimed to:

Kowa Genesis D (K050271)
Precision Optics Corporation, Inc. Digital Ophthalmoscope (K053425)
Welch Allyn 11720 Ophthalmoscope (K950461)
Discam Digital Imaging System (K974535)

The EyeQuick Digital Ophthalmoscope is substantially equivalent to the predicate devices with regard to intended use, operating principle and function.

Description

The EyeQuick Digital Ophthalmoscope Camera is an ophthalmoscope with an integrated digital camera. The system includes an LCD viewfinder and can be used handheld without any cables. The Digital Ophthalmoscope has on board memory to store images which can be downloaded to a PC via a USB connection.

Intended Use

The EyeQuick Digital Ophthalmoscope Camera is intended for use in capturing approximately eight degrees narrow angle field of view images of the eyelids, retina and the anterior segment of the eye.

Performance

The EyeQuick Digital Ophthalmoscope has been tested and has met all the necessary requirements for ISO 10940, IEC 60601-1, IEC 60601-1-2, and EN55011. The device meets the requirements for safe radiation emission.

Conclusion

All testing deemed necessary including requirements set forth in device industry International Standards have been conducted to ensure that the EyeQuick Digital Ophthalmoscope Camera is safe and effective for its intended use, when used according to its instructions for use. Equivalence to identified predicate devices has been established.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

EyeQuick, LLC
c/o Marc Ellman, MD
Manager
1400 Common Drive
El Paso, TX 79936

JUN 23 2011

Re: K102412
Trade/Device Name: EyeQuick Digital Ophthalmoscope Model 1000
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic Camera, AC-Powered
Regulatory Class: Class II
Product Code: HKI
Dated: June 14, 2011
Received: June 20, 2011

Dear Dr. Ellman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Kesia Alexander

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K102412

Indications for Use Statement

510(k) Number (if known): K102412

Device Name: EyeQuick Digital Ophthalmoscope Camera

Indications for Use:

The EyeQuick Digital Ophthalmoscope Camera is intended for use in capturing approximately eight degrees narrow angle field of view images of the eyelids, retina and the anterior segment of the eye.

Prescription Use ____X____ or Over-The-Counter Use _____

(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

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